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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,868	01/17/2001	Craig A. Rosen	PTZ32	6804

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EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/764868	Craig Rosen et al.
Examiner	**Group Art Unit**
Diana Johannsen	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-24 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Detailed Action

Office Action Summary

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14-15, and 21 drawn to polynucleotides, vectors, host cells, and methods of making protein, classified in at least for example, Class 536, subclass 23.1.

II. Claims 11-12 and 16, drawn to polypeptides, classified in at least for example Class 530, subclass 350.

III. Claim 13, drawn to antibodies, classified in at least for example Class 530, subclass 387.1.

IV. Claim 17, drawn to a method of treating, preventing, or ameliorating a condition using nucleic acids, classified in at least for example Class 514, subclass 44.

V. Claim 18, drawn to a method of diagnosing a pathological condition using nucleic acids, classified in at least for example Class 435, subclass 6.

VI. Claim 19, drawn to a method of diagnosing a pathological condition using polypeptides, classified in at least for example Class 435, subclass 7.1.

VII. Claim 20, drawn to a method of identifying a binding partner, classified in at least for example Class 435, subclass 7.1.

VIII. Claim 22, drawn to a method of identifying an activity in a biological assay, classified in at least for example Class 435, subclass 69.1.

IX. Claim 23, drawn to a structurally undefined protein product, classified in at least for example Class 530, subclass 324.

X. Claim 24, drawn to a method of treating, preventing, or ameliorating a condition using a polypeptide, classified in at least for example Class 514, subclass 2.

Sequence Election Requirement Applicable to All Groups

2. It is noted that each Group detailed above reads on numerous patentably distinct molecules. MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus

deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*

3. The numerous SEQ ID NOS encompassed by the instant claims are patentably distinct by virtue of having different structures and encoding or depicting different proteins. As set forth above, these molecules are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. A reference against one molecule would not be a reference against another, and, in view of this and the multitude of sequences submitted for examination by the USPTO, a search of SEQ ID NOS encoding or depicting more than one distinct protein would pose a serious burden. Accordingly, a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO. Applicant must specifically identify each of the corresponding SEQ ID NO: X, SEQ ID NO: Y, and Clone ID NO: Z for the sequence elected.

This is not an election of species. Applicant is advised that examination will be restricted to only the elected SEQ ID NO.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, and IX are drawn to patentably distinct because they are drawn to chemically and biologically distinct molecules having different structures and functions. The nucleic acids of Invention I are composed of nucleotides linked by phosphodiester bonds and function in, e.g., methods of hybridization. The proteins and antibodies of Inventions II and IX, and III, are each composed of amino acids linked by peptide bonds. However, the molecules have different functional properties and

structural requirements. Particularly, the antibodies of Invention III are glycosylated, have a particular tertiary structure, and have particular binding properties that render them distinct from other proteins. It is also noted that the nucleic acids of Invention I are not required to produce the proteins of Invention II or IX, which may be chemically synthesized or isolated from nature.

Inventions I and IV, I and V, and I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Invention I may be used in a materially different process, such as methods of making protein.

Inventions I and VI, I and VII, and I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Invention I are not disclosed as capable of use in the methods of Inventions VI, VII, or X, and function in methods that are materially distinct and have different effects such as methods of nucleic acid hybridization.

Inventions II and IV, II and V, II and VIII, III and IV, III and V, III and VIII, IX and IV, IX and V, and IX and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins and antibodies of Inventions II, III, and IX are not disclosed as capable of use in the methods of Inventions IV, V, and VIII, and function in methods that are materially distinct and have different effects, such as methods of protein detection employing antibodies.

Inventions II and VI, II and VII, II and X, IX and VI, IX and VII, and IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Inventions II and IX may be employed in materially distinct methods, such as methods of making antibodies.

Inventions III and VI and III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Invention III may be employed in materially distinct methods, such as methods of protein purification.

Inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case, the antibodies of Invention III are not disclosed as capable of use in the treatment methods of Invention X, and function in methods that are materially distinct and have different effects, such as methods of protein purification.

Inventions IV, V, VI, VII, VIII and X are drawn to patentably distinct methods having different objectives and/or requiring different reagents and different process steps. Invention IV requires, e.g., a step of administering a polynucleotide to achieve the objective of treatment. Invention V requires, e.g., a step of detecting a mutation in a polynucleotide to achieve the objective of diagnosing a condition. Invention VI requires, e.g., a step of detecting the amount of a polypeptide to achieve the objective of diagnosing a condition. Invention VII requires, e.g., a step of contacting a polypeptide with a binding partner to achieve the objective of detecting a binding partner. Invention VIII requires, e.g., a step of expressing a nucleic acid to achieve the objective of identifying an activity. Invention X requires, e.g., a step of administering a polypeptide to achieve the objective of treatment. Accordingly, the methods of each of Inventions IV, V, VI, VII, VIII and X are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-X require different literature and sequence searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. A fully responsive reply will comprise the election of both a group and a particular sequence to be examined.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
June 30, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600